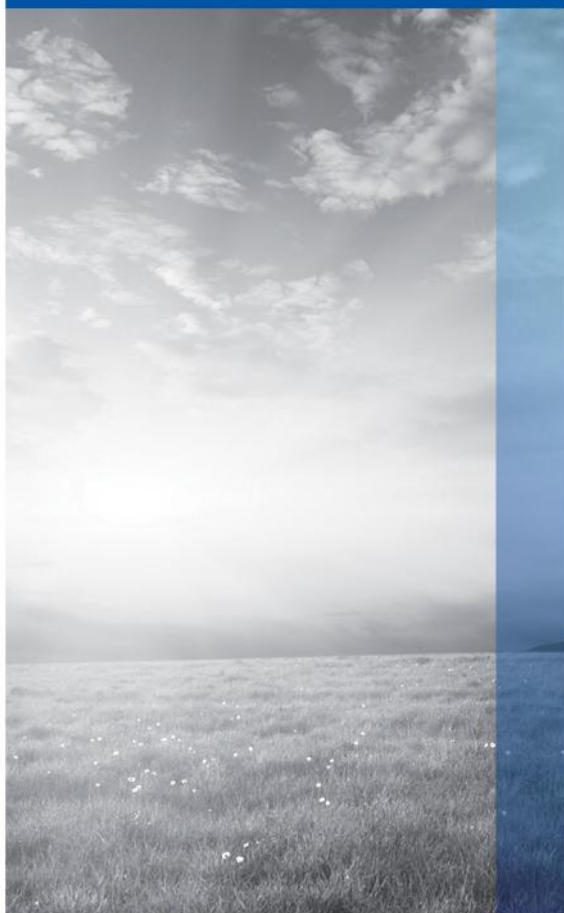


Important Field Safety Notice



Possible risk of a collision when you use XVI and an external beam limiting device

Product: XVI

Date: November 2013

FCO: 200 01 507 081



ELEKTA

Important Field Safety Notice



We are providing the information in this Notice to notify you of an important safety issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.

We also need you to acknowledge and accept this FCO by signing and returning the statement on the FCO Action Notification Report.

We advise you to insert this Notice in the applicable copy of the User Manual.

Possible risk of a collision when you use XVI and an external beam limiting device

Product: XVI

Date: November-2013

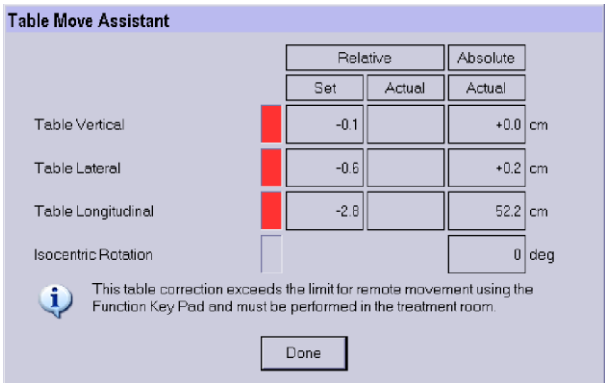
FCO: 200 01 507 081

Scope:	XVI R4.2.1, R4.5, R4.5.1, and R5.0
Description:	XVI can incorrectly calculate the target position of the treatment table, because of an error that does not occur very frequently. This is the sequence of events when this error occurs: - You do an online VolumeView™ acquisition and registration. - You accept the registration and the Table Move Assistant dialog box appears. - The Relative Actual column of the Table Move Assistant dialog box incorrectly appears blank. - When this occurs, XVI does not read the Absolute Actual position of the treatment table. This causes XVI to calculate the treatment table moves from the zero position of the treatment table (+0.0,+ 0.0,+0.0). - In XVI R5.0, if the Relative Set values are less than or equal to ± 2.5 cm (for earlier releases of XVI, the value is ± 2 cm), you can do remote automatic table movement (RATM) from the function keypad (FKP). - When you press the Table ASU (automatic setup) buttons, the treatment table moves to a position that was incorrectly calculated from XVI.

This Notice has been notified to the appropriate Regulatory Authorities

Important Field Safety Notice



Clinical impact:	If you do not monitor the patient and treatment table movements, and you keep the Table ASU buttons pressed, the treatment table continues to move. It only stops when a touchguard activates. Therefore, this error can cause a collision between the patient and an external beam limiting device (BLD) if: • The external BLD does not operate with the touchguard attached. • The external BLD extends out more than the touchguard. If this error occurs with an external BLD attached to the digital accelerator, you can cause fatal injury to the patient. When the error occurs, it is not possible to get the Table Move Assistant values in tolerance. Therefore, it is not possible to apply an incorrect correction to the patient position before treatment delivery.
Solution:	Monitor the Relative Actual column (see Figure 1) of the Table Move Assistant dialog box.  Figure 1: Table Move Assistant dialog box If the Relative Actual column is blank, do not press the Table ASU buttons on the FKP. To correct the error: 1. Close the XVI program. 2. Shutdown and restart the XVI control system. 3. Put the patient in their initial setup position. 4. Acquire the VolumeView™ again, and continue the usual workflow. Always monitor the patient when you do RATM. When you do VolumeView™ acquisitions with an external BLD attached, make sure that the stop angle of the VolumeView™ parameters is in the lower half of the gantry rotation. This decreases the risk of a collision with the patient. A later software release of XVI will give a solution to this problem.
Technical Reference:	CLM 01690462

This Notice has been notified to the appropriate Regulatory Authorities

Important Field Safety Notice



Contact:	If you have any queries about this Notice, please contact your local Elekta office.
----------	---

Safety reference

The following warnings and cautions are associated with this notice:



WARNING

Make sure that the gantry and treatment table movements are in view at all times when you do ASU. If you ignore this warning, it can cause fatal injury and clinical mistreatment.



WARNING

Make sure that collisions between persons and equipment do not occur if you use ASU to activate the gantry and table isocentric movements. Be more careful in these conditions. If you ignore this warning, it can cause fatal injury and clinical mistreatment.

This Notice has been notified to the appropriate Regulatory Authorities

FCO Action Notification Report

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this FCO has been provided to address a safety issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.**

Classification:	Important Field Safety Notice	FCO Ref:	200 01 507 081
FCO description:	Possible risk of a collision when you use XVI and an external beam limiting device		
Scope:	XVI R4.2.1, R4.5, R4.5.1, and R5.0		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	Location or Site No:

Acknowledgement by customer*: This notification to be signed by the customer I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:	
Name:	Title:
Signature:	Date:

New installation confirmation: This notification to be signed by the installing Elekta or Representative employee	
Name:	Title:
Signature:	Date:

This Notice has been notified to the appropriate Regulatory Authorities